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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,749	09/21/2001	Thomas E. Borillo	593/005	5029
1473	7590	12/30/2003	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/30/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/960,749	BORILLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 September 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-35 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 28-35 and 37-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)  
 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 28, 33 and 35 were objected to for minor informalities. Correction is noted and the objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

2. Claims 28-38 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 28-35 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al. '144 in view of U.S. Patent No. 5,797,960 to Stevens et al.

Regarding claims 28, 29 and 35-38, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly (apparatus 150); a shaft (member 161); and a positioning tube (shaft 174) with a positioning guide member on an end (members 155); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said

positioning guide to a location about the ostium of said appendage (FIGS 21 and 22); deploying said positioning guide to engage atrial wall portions (FIG. 22); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 21). Lesh does not disclose an outer tube assembly with securement means to engage surface portions of a septum traversed by the outer tube. Stevens teaches that an outer tube with securement means is provided to allow the introduction of instruments for visualization and intervention through the outer tube and to provide a securement means that prevents leakage of blood (Column 13 lines 24-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube assembly of Lesh with an outer tube in order to facilitate the insertion of instruments into the heart and to seal the opening in the heart from blood leakage.

Regarding claims 30 and 31, Lesh discloses that said reversibly expandable structure comprises providing at least a preformed wire configuration (members 155 and Column 13 lines 41-47).

Regarding claim 32, Lesh discloses that said positioning guide further comprises providing a positioning guide having a reversibly expandable structure comprising an inflatable balloon (inflatable member 114).

Regarding claim 33, Lesh discloses that said tube assembly further comprises providing a lumen (Column 11 lines 27-38).

Regarding claim 34, Lesh discloses that the step of providing said tube assembly further comprises providing a delivery tube (shaft 151) for advancing said positioning guide through said tube assembly to a location proximate to said appendage (FIG. 21), and wherein said delivery tube retractably extends through said outer tube.

***Response to Arguments***

5. Applicant's arguments filed September 29, 2003 have been fully considered but they are not persuasive.
6. Applicant argues that Stevens '960 does not require that the shaft be fixed relative to the walls of the heart. However, Stevens '960 provides securement means on both sides of the cardiac wall (FIG. 2C) and therefore the shaft is fixed relative to the walls of the heart.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

*JRB*  
Jrb

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700